K112997

DEC 17 2011

Silicon Valley Medical Instruments Inc.™

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name:	Silicon Valley Medical Instruments, Inc.
Address	47697 Westinghouse Drive, Suite 101, Fremont, CA 94539-7401 USA
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Establishment Registration Number	N/A – Not yet registered.
Contact Person	Richard E. Anderson; VP, RA/QA (richarda@svmii.com)
Date Prepared	7 October 2011

Name of Device	
Trade or Proprietary Name	HD-IVUS Ultrasound Imaging System
Common or Usual Name	System, Imaging, Pulsed Doppler, Ultrasonic (IYN); System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Classification Name	Class II
Classification Panel	Cardiovascular
Regulation	21 CFR 892.1550 (IYN); 21 CFR 892.1560 (IYO)
Product Code(s)	IYN; IYO
Legally Marketed Device(s) to which Equivalence is Claimed	Boston Scientific Corporation's iLab Ultrasound Imaging System (Cleared 14Jul05 via K051679)
Reason for Submission	New device
Device Description	The HD-IVUS Ultrasound Imaging System is a minimally invasive intravascular ultrasound diagnostic imaging tool when used in conjunction with an intravascular ultrasound catheter. The System is a medical device for use by or on the order of a physician. The HD-IVUS Ultrasound Imaging System is comprised of a System Console with a touch screen monitor, a Roll Stand, a Patient Interface Module (PIM), a Power Supply, and an Intravascular Ultrasound Catheter (510(k) cleared and sold separately). The Catheter emits sound energy from a transducer at the distal tip of the catheter, which is guided into the coronary arteries of the heart. Sound waves that reflect from the inner vascular tissues are received by the transducer and sent to the System

	Console where a high resolution, cross-sectional image is displayed in real time. The technique provides for in-vivo visualization of the coronary artery lumen, coronary artery wall morphology, and devices (such as stents) at or near the surface of the coronary artery wall. • **System Console** The HD-IVUS system features a point-of-care system console that is mounted to a roll stand. The System Console is the central component that is responsible for: • managing the generation and display of IVUS images • storing and exporting the image data • providing the main user interface • providing analysis tools (i.e., area measurements, linear measurements, and annotations) The System Console receives, processes, displays, and records ultrasound image data from the transducer in the Kodama HD-IVUS catheter. The IVUS images are displayed on a high-resolution, 19-inch, flat panel, touch screen monitor. The monitor serves as the graphical user interface (GUI) for operating the system. All system information and controls are located on the touch screen monitor. The HD-IVUS system has internal storage for 25 studies. Each study can have up to eight loops, with a maximum of 9000 frames per loop. Study data is saved in DICOM format and can be exported to DVD, using the integrated DVD drive, or to a USB storage device, using one of the two USB ports. • **Roll Stand** The variable height roll stand supports the System Console and enables the console to be attached to a mobile stand that can be rolled up to the patient bed. • **Patient Interface Module (PIM)** The Patient Interface Module (PIM) provides the electromechanical interface between the catheter and the system console. The PIM provides the mechanical interface to secure the catheter, as well as the mechanical energy to rotate the catheter's imaging assembly. The PIM also provides the electrical interface that transmits the

	signal from the integrated ultrasound generator to the catheter and receives the return signal. When placed in a sterile bag, the PIM can be situated near the patient in the sterile field. The PIM features an imaging on/off button and a recording on/off button, which enable the physician to start or stop imaging and recording from within the sterile field. An orange LED light on the PIM indicates active recording. • **Power Supply** The system includes a universal, medical grade, external power supply that enables direct connection to the hospital power source. • **Intravascular Ultrasound Catheter (510(k) cleared and sold separately)** The Kodama Intravascular Ultrasound Catheter is a minimally invasive intravascular ultrasound coronary imaging catheter. The catheter emits acoustic energy from a transducer at its distal tip, which is guided into the coronary arteries of the heart. Sound waves that are reflected from vascular tissues are received by the transducer and sent through the PIM to the system console. The catheter can be operated at two different frequencies, 40 MHz or 60 MHz, depending on user preference. An integrated telescope allows the imaging of multiple regions of interest in a single procedure by advancing or retracting the imaging assembly without moving the catheter sheath. (NOTE: *Refer to the Directions for Use supplied with the Kodama Intravascular Ultrasound Catheter for additional information.)*
Intended Use of the Device	The HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only.
Indications for Use	The HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Summary of the Technological Characteristics of the Device Compared to the Predicate Device		
Characteristic	**Predicate** (Boston Scientific Corporation's iLab Ultrasound Imaging System – Cleared 14Jul05 via K051679)	**New Device** **(SVMI's** HD-IVUS Ultrasound Imaging System)

Signal Type	Doppler, Echo	Doppler, Echo
Catheter Mechanical Drive	Patient Interface Module (PIM) (cleared with ultrasound system)	Motor Drive Unit (MDU) (cleared with ultrasound system)
Signal Conductor	Coaxial wire traveling down catheter	Coaxial wire traveling down catheter
Signal Generator/ Receiver Materials	PZT crystal transducer	PZT crystal transducer
Acoustic Output	Does not exceed Track 3 limits	Does not exceed Track 3 limits
Ultrasound Frequency	40 MHz, 60 MHz ± 10%	10 – 40 MHz ± 10%
Method of Use	Intravascular	Intravascular
User Interface	PC-based system with keyboard and touch screen and mouse	PC-based system with keyboard and touch screen and mouse
Software Interface	Custom GUI	Custom GUI
Intended Use	The HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	The iLab Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Performance Data		
Summary of Non-clinical tests Conducted for Determination of Substantial Equivalence		
Performance Test Summary – New Device		
Characteristic	**Standard/Test/FDA Guidance**	**Results Summary**
Electromagnetic Compatibility	IEC 60601-1-2.	Compliant with IEC 60601-1-2.
Electrical Safety and Acoustic Safety	IEC 60601-1, IEC 60601-1-4, and IEC 60601-2-37.	Compliant with IEC 60601-1, IEC 60601-1-4, and IEC 60601-2-37.

Conclusions Drawn from Design Verification/Validation and Non-clinical Data
The HD-IVUS Ultrasound Imaging System is substantially equivalent in design and technology to the predicate device(s) with regard to intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Richard E. Anderson
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FREMONT CA 94539-7401

DEC 17 2011

Re: K112997
Trade/Device Name: HD-IVUS Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN and IYO
Dated: October 7, 2011
Received: October 7, 2011

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K112997

Device Name: SVMI's HD-IVUS Ultrasound Imaging System

Indications for Use:

Silicon Valley Medical Instrument's HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number: K112997

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: SVMI HD-IVUS Console
Transducer: SVMI Kodama Catheter

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)	P						
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging